IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: TRICOR DIRECT PURCHASER ANTITRUST LITIGATION	)	
THIS DOCUMENT RELATES TO: C.A. Nos. 05-340, 05-351, 05-358	)	C.A. No. 05-340 (KAJ) REDACTED

DEFENDANTS' ANSWERING BRIEF IN OPPOSITION TO DIRECT PURCHASER CLASS PLAINTIFFS' OPENING BRIEF IN SUPPORT OF THEIR MOTION FOR CLASS CERTIFICATION

Attorneys for Abbott Laboratories:

Mary B. Graham (I.D. #2256)
James W. Parrett, Jr. (#4292)
MORRIS, NICHOLS, ARSHT & TUNNELL
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19801
302.658.9200

OF COUNSEL:

William F. Cavanaugh, Jr.
Thomas W. Pippert
Chad J. Peterman
Alexis A. Gander
PATTERSON, BELKNAP, WEBB TYLER LLP
1133 Avenue of the Americas
New York, NY 10036-6710
212.336.2000

Attorneys for Fournier Industrie et Santé and Laboratoires Fournier S.A.:

Frederick L. Cottrell, III (I.D. #2555)
Anne Shea Gaza (I.D. #4093)
cottrell@rlf.com
gaza@rlf.com
RICHARDS, LAYTON & FINGER
One Rodney Square
Wilmington, DE 19801
302.651.7700

OF COUNSEL:

Steven C. Sunshine
Maria M. DiMoscato
CADWALADER, WICKERSHAM & TAFT LLP
1201 F Street, N.W.
Washington, D.C. 20004

Matthew P. Hendrickson
Bradley J. Demuth
CADWALADER, WICKERSHAM & TAFT LLP
One World Financial Center
New York, NY 10281

Timothy C. Bickham
STEPTOE & JOHNSON LLP
1330 Connecticut Avenue, N.W.
Washington, DC 20036-1795

Dated: August 16, 2006

Redacted Filing Date: May 13, 2008

TABLE OF CONTENTS

TABLE OF CITATIONS

PRELIMINARY STATEMENT

To avoid needless repetition, defendants incorporate by reference the memorandum submitted in opposition to the Indirect Purchaser class certification motion. Unlike the Indirect Purchaser Plaintiffs ("IP Plaintiffs"), the Direct Purchasers ("DP Plaintiffs") seek to certify a class under only Sections 1 and 2 of the Sherman Act. But this limitation does not salvage the DP Plaintiffs' putative class because it suffers from some of the same flaws.

The first flaw is that, like the IP Plaintiffs, the DP Plaintiffs argue that class certification is appropriate because they are pursuing an "overcharge" theory. But such a theory makes no economic sense under the plaintiffs' own assumptions and allegations.

In plaintiffs' assumed "but for" world, defendants would not have introduced either a 160 mg TriCor tablet in 2001 or a 145 mg TriCor NFE tablet in 2004. Instead, defendants would have continued to offer only the TriCor 200 mg capsule, and in April 2002, an AB-rated generic 200 mg capsule would have entered the marketplace. As a result, plaintiffs contend, TriCor prescriptions have begun to be filled, in most instances, with AB-rated 200 mg fenofibrate generics introduced by Teva and others. However, in that "but for" world, Abbott would not have continued to detail TriCor 200 mg to physicians, providing samples and reminding them of the merits of TriCor in comparison to other prescription drugs for dyslipidemia.

The result is that total prescriptions for TriCor 200 mg capsules *and* its AB-rated generic versions would have stalled and dropped—not continued to grow to the more than 10 million annual fenofibrate prescriptions that exist today. In the absence of defendants' promotional efforts, there would have been virtually no promotion of fenofibrate in the United States. Physicians respond to promotion, and would have prescribed other drugs to patients with dyslipidemia, such as the heavily promoted and marketed statins.

Plaintiffs' motion for class certification is based on their expert's REDACTED

See May 8, 2006 Declaration of Jeffrey J. Leitzinger ("Leitzinger Decl.") at p. 8. This requires a comparison of the price of branded TriCor in the actual world with the price of branded TriCor in the "but for" world. But, in the "but-for" world, millions of the TriCor prescriptions plaintiffs assume in the "but for" world would not have been TriCor prescriptions—they would have been prescriptions for statins and other highly-promoted cholesterol drugs. For direct purchasers (*e.g.*, wholesalers)—who contend that they purchase drugs in response to their customers' demand— the broad market shift to statins would require them to buy statins, not fenofibrate, making an overcharge theory untenable.

The second fundamental flaw in plaintiffs' motion is that there are members of the DP class that had the ability to influence whether TriCor or an alternative fenofibrate product was dispensed to a patient. For the entire proposed class period, physicians have had a wide choice of prescription drugs (statins, fibrates, bile acid sequestrants, and niacins) to treat their patients' dyslipidemia. In addition, for all of the alleged class period, the same "molecule" (fenofibrate) has been available from Abbott *and* from Teva. Abbott markets its fenofibrate under the brand name TriCor. Teva markets fenofibrate under the brand name Lofibra. Other fenofibrates (Antara and Triglide) are also now available.

Retail drug stores often implement "switching programs" and have argued that their ability to convert a patient from one drug to another drug is greatest when the conversion involves the same drug molecule (*e.g.*, fenofibrate). The DP Plaintiffs make much of the fact that their class is largely comprised of wholesalers which, they contend, are completely subject

to "derivative demand," but they ignore the fact that large and powerful retail and mail-order pharmacies (Wal-Mart, Medco) are also members of the class.

Moreover, the small regional wholesalers that seek to represent the DP Plaintiffs' Class may simply have to rely on "derivative demand." But lurking behind these class representatives are three large national wholesalers which dominate these claims. REDACTED

According to their websites, they have developed aggressive marketing programs which attempt to influence demand for competing generic drugs. Given plaintiffs' allegations that the new TriCor formulations were no better than the initial TriCor 200 mg product, there appears to be no reason why these wholesalers could not have attempted to influence demand between competing same-molecule products like Antara, Lofibra, and TriCor. The extent to which they could have done so or considered doing so requires an individualized inquiry before a fact finder can determine whether a direct purchaser was injured at all—and, if so, the amount of damages to which it would be entitled. Moreover, these "Big Three" wholesalers actually stood to *profit* from the absence of an AB-rated generic alternative on the market, which means that they were not injured by the alleged conduct. Plaintiffs therefore cannot demonstrate that antitrust injury is "common" to all members of the class, or demonstrate injury or damages on a class-wide basis.

Accordingly, the Direct Purchaser Plaintiffs' motion for class certification should be denied. At a minimum, the Court should permit Defendants to conduct discovery of these significant, but unnamed, class members.

STATEMENT OF FACTS

A. The Dyslipidemia Market and TriCor.

Defendants respectfully refer the Court to Defendants Indirect Purchaser Brief which provides the relevant background facts.[1]

B. Plaintiffs' "But For" World.

Plaintiffs' descriptions of the alleged "but-for" world are contradictory. In their Complaint, Plaintiffs contend that Abbott's introduction ***both*** of the first tablet product in 2001, and of the NFE tablet in 2004 were anticompetitive and improper. Therefore, in a "but-for" world in which no anticompetitive activities occurred, no new branded fenofibrate product would have entered the market after the launch of the first 200 mg capsule.

But Plaintiffs' expert Dr. Leitzinger asserts that the "but-for" world includes an REDACTED *See* Leitzinger Decl. at p. 8 (stating that he REDACTED

This assumption is inconsistent with the allegations of the Complaint, which asserts that the introduction of the branded tablet was wrongful. In a "but-for" world without allegedly wrongful activity, the branded tablet would never have entered and therefore would have been no opportunity—or possibility—for a generic

[1] While the likelihood of the plaintiffs' success on the merits is not relevant to the issue of whether certification is proper, *Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 177-78 (1974), an inquiry into facts relevant to class certification is required. *See, e.g., Thorn v. Jefferson-Pilot Life Ins. Co.*, 445 F.3d 311, 319 (4th Cir. 2006) ("At the class certification phase, the district court must take a 'close look' at the facts relevant to the certification question and, if necessary, make specific findings on the propriety of certification."); *General Telephone Co. of Southwest v. Falcon*, 457 U.S. 147, 160 (1982) ("[S]ometimes it may be necessary for the district court to probe behind the pleadings before coming to rest on the certification question.").

company to launch an "AB-rated" tablet. Because a "but-for" world in which no reformulated products are introduced, and the 200 mg capsule remains the only branded product on the market is the *only* "but-for" world that is consistent with the allegations of the Complaint, for the purposes of class certification defendants have adopted that definition.

The problem with plaintiffs' approach is that in the real world there were roughly

REDACTED

Plaintiffs' overcharge model assumes the same growth for TriCor and its AB-rated generics in a world with no new TriCor formulations introduced and no TriCor brand marketing over the last four years. Plaintiffs also assume that TriCor and its AB-rates generics are "fungible" on an economic scale. But fenofibrate usage would not have grown, it would have shrunk. In other words, REDACTED

Physicians would have prescribed one of the competing cholesterol drugs that dominate the market. Plaintiffs' proposed "but for" world is thus at odds with their "overcharge" theory of damages.

C. The Proposed "Direct Purchaser" Class.

Plaintiffs have proposed a class comprising:

> All persons or entities in the United States who purchased TriCor in any form directly from any of the Defendants at any time during the period April 9, 2002 , through the present.

Amended Complt. at 2. REDACTED

The named plaintiffs in this action are two wholesalers (Louisiana Wholesale and Rochester Drug Co-Operative) and the assignee of a wholesaler (Meijer, assignee of the claims

of Frank Kerr).[2] None of the other categories of Abbott's direct-purchasing customers is represented. REDACTED

These small wholesaler class representatives seek to represent other direct purchasers whose business operations are fundamentally different from the operation of a small wholesale drug business: retail drug stores large and small, mail order pharmacies (owned by pharmacy benefit managers), hospitals, and nursing homes.

The operation of each of these businesses are, in turn, very different from one another. Historically, retail drug stores have simply dispensed what a physician prescribed. Some retailers have sought to change that largely passive role. Retail drug stores saw managed health care's ability to secure discounts from manufacturers based on their duty to influence physician prescribing decisions. Retailers, both large and small, contended in class-action and opt-out litigation that retailers had the ability to influence physician prescribing decisions both directly, by intervening with the physician, and indirectly, through the customer who came to their pharmacies to fill their prescriptions. *See In re Brand Name Prescription Drugs Antitrust Litigation*, 1996 WL 167350 *15 (N.D. Ill. 1996) ("the plaintiffs also dispute the Manufacturers' claims that retail pharmacies cannot affect market share . . . In sum, the plaintiffs have demonstrated that, provided with the proper incentives, the retail pharmacies can and do have some ability to move market share"). REDACTED

[2] The impropriety of Meijer's assertion of assigned claims is addressed in Point IV, *infra.*

REDACTED

In the case of TriCor, there is one major retail chain that buys TriCor and that has not opted out of the class – Wal-Mart.

See Ex. 3 (Jones Decl.) at ¶ 24. As demonstrated at trial in the ***Brand Names Prescription Drug Antitrust Litigation***, in the mid-1990s, Wal-Mart had a policy in which it would seek to switch patients prescribed one drug to a competing drug provider if it was the same chemical entity. *See* ***In re Brand-Name Prescription Drugs Antitrust Litigation***, No. 94-C-897, Trial Transcript at 464-65 (N.D. Ill. September 23, 1998) (discussing 1994 policy memo to all Wal-Mart pharmacists describing policy to "switch" single chemical entity products). Lofibra and TriCor are the same chemical entity, as are TriCor and Antara, and TriCor and TriGlide. The reason they are not AB-rated is because the dosage is different. Thus, under Wal-Mart's policy as it existed in the 1990s, it would be amenable to a program wherein it would convince physicians and patients to switch from TriCor to Lofibra—or to another fenofibrate product like Antara or TriGlide.

REDACTED

Medco is also an unnamed class member. Medco is the mail order pharmacy component of one of the country's most powerful Pharmacy Benefit Managers ("PBMs"). Medco has long been able to extract discounts from pharmaceutical manufacturers because of its ability to influence prescribing behavior. REDACTED

See Ex. 3 (Jones Decl.) at ¶ 27; Ex 8 (Abbott TriCor 00086863-464). Thus, Medco is not wholly dependent on downstream demand. Medco directly impacts demand and pricing. Medco's operation could hardly be more different than the operations of two small regional wholesalers.

The small wholesalers put forth as class representatives are not representative of the drug wholesale business, which is dominated by three major national wholesalers: (1) Amerisourcebergen (2) Cardinal and (3) McKesson (collectively, the "Big Three"). REDACTED Defendants sought to take discovery of these unnamed class representatives, but the Court denied this request. However, even a review of publicly available information indicates just how different they are from the small wholesalers put forth as putative class representatives.

The putative class representatives testified REDACTED

See Ex. 4 (Deposition of Meijer Inc. by Jacquelyn DeBruler) at 32; Ex.

5 (Deposition of Louisiana Wholesale Drug, Inc. by Gayle White) at 80; Ex. 6 (Deposition of Rochester Drug Cooperative by Larry Doud) at 31.

The three national major wholesalers, however, claim the ability to influence downstream demand for competing prescription drugs. The "big three" advertise their ability to assist manufacturers in moving share to their pharmaceutical products. *See* Amerisourcebergen website, http://www.amerisourcebergen.com /cp/1/markets/ suppliers/ generics/hot_topics/ prxo_generics/index.jsp (visited August 12, 2006). Amerisource cites its ability to work with retailers to engage in promotional activities. *Id.* ("We have the buying power of over 12,000 pharmacies and growing. Suppliers are able to take advantage of marketing opportunities including promotions, blast faxing as well as our Retail Edge publication to help promote product awareness to our PRxO Generics members.").

Similarly, McKesson touts its capacity to implement programs that involve communicating with patients on drug utilization and assisting retailers in driving "market share" from one drug to another. *See* McKesson Website, at http://www.mckesson.com/en_us/ McKesson.com/ For%2BManufacturers/ Pharmaceutical/ Consumer%2BPatient%2BMarketing/ Consumer%2Band% 2BPatient%2BMarketing %2BPrograms.html (visited August 14, 2006) ("McKesson and our pharmacy customers are committed to improving patient compliance and persistency. We can work with you to help promote loyalty to your brands while helping patients optimize their therapies. Our capabilities include…Formulary optimization…") and http://www.mckesson.com/ en_us/ McKesson.com/ For%2BManufacturers/ Pharmaceutical/ Pharmacy% 2BMarketing% 2BPrograms/ Pharmacy%2BMarketing%2BPrograms.html (visited August 14, 2006) ("McKesson's retail programs drive volume and can help your organization maintain and grow your share of the market. Our pharmacy customers recognize their role in

encouraging patients to stay with their therapies, and deliver valuable counseling services right at the pharmacy counter. McKesson supports pharmacists in their counseling efforts, with… Compliance and persistency programs, OTC/Rx cross-marketing programs, Promotional and market-share programs…"); *see also* Cardinal Health website, http://www.cardinal.com/ pts/ content/ commerce/ logdis/ Generics.pdf (visited August 14, 2006) and http://www.cardinal.com/ pts/ content/ commerce/ logdis/ Pharmacy.pdf (visited August 14, 2006) (advertising that Cardinal can help manufacturers "increase [their] marketshare by increasing pharmacists' awareness…"). While these programs may be used primarily to move share between competing generic products, there is no reason that these major wholesalers could not attempt to use the same tools to move share between competing same-molecule products like Antara, Lofibra, and TriCor, particularly given the allegations they have made in this case.

ARGUMENT

I. PLAINTIFFS BEAR THE BURDEN OF SHOWING THAT THE PROPOSED CLASS SATISFIES EACH OF THE REQUIREMENTS OF THE FEDERAL RULES OF CIVIL PROCEDURE.

Plaintiffs bear the burden of proving that the proposed class meets each and every one of the prerequisites for class certification. *See Davis v. Romney*, 490 F.2d 1360, 1366 (3d Cir. 1974). Moreover, plaintiffs must demonstrate that the class mechanism is a superior method for the adjudication of their claims and that the case is "manageable" as a class action, in light of all possible variations in fact, laws, and proof. In reviewing plaintiffs' arguments, this Court must apply a "rigorous" analysis. *See In re Currency Conversion Fee Antitrust Litig.*, 230 F.R.D. 303, 306 (S.D.N.Y. 2004) *citing Gen. Tel. Co. v. Falcon*, 457 U.S. 147, 161 (1982); *accord Caridad v. Metro-North Commuter R.R.*, 191 F.3d 283 (2d Cir. 1999).

None of the prescription drug cases touted by plaintiffs as "analytically identical cases" for purposes of class certification (Pl's Brief at 2) addresses the unique combination of facts in this case. After conducting the rigorous analysis of plaintiffs' motion mandated by the United States Supreme Court in *Falcon*, this Court should deny plaintiffs' motion on the basis of those facts.

II. PLAINTIFFS HAVE NOT SHOWN THAT THEY CAN PROVE INJURY OR DAMAGES ON A "CLASS-WIDE" BASIS.

Plaintiffs' claims fail to satisfy the requirements of the Federal Rules of Civil Procedure because plaintiffs have not provided a valid class-wide basis for proving injury or damages.

A. Plaintiffs' "overcharge" theory is not applicable to the unique facts of this case.

Plaintiffs directed their expert Dr. Leitzinger to assume that this is an "overcharge" case, and he based his analysis of the appropriateness of class certification on that assumption. *See* Leitzinger Decl. at 8.

REDACTED

Plaintiffs' approach makes no economic sense on the facts of this case, facts that Dr. Leitzinger simply ignored. REDACTED

. *See* Ex. 1 (Sherry Report) at ¶¶ 79-82; 90-103. This approach simply does not withstand scrutiny. In the "but for" world of dyslipidemia drugs, under plaintiffs' assumptions, the overwhelming number of prescriptions would be written for statins— not for TriCor or AB-related generic versions of TriCor. As a consequence, any injury to direct purchasers of TriCor would be their "lost profits"—not a purported "overcharge."

[3] REDACTED

The flaw in plaintiffs' approach is most visible when a purchase of TriCor in the actual world is compared to a purchase of a statin in the "but-for" world. But the flaw also exists when a purchase of TriCor in the actual world is compared to a purchase of an AB-rated generic in the "but-for" world. REDACTED

See Ex. 1 (Sherry Report) at ¶¶ 86-99.

REDACTED

REDACTED

Plaintiffs simply assume that the balance of prescriptions as between TriCor and an AB-rated generic would be different. The flaw in this approach, of course, is that in the "but for" world the DP Plaintiffs would not have purchased fenofibrate in most instances. Under plaintiffs' own theory, no new TriCor formulations would not have been introduced and, as a result, fenofibrate sales would have been largely replaced with sales of generics by the spring of 2002. REDACTED

Absent this growing demand for fenofibrate, patients would have been prescribed other drugs, such as the heavily promoted and marketed statins. REDACTED

REDACTED

It is well-settled that an economic model in an antitrust case must bear some reasonable relationship to the real world. *See Eastman Kodak Co. v. Image Technical Services, Inc.*, 504 U.S. 451, 466-67 (1992) ("Legal presumptions that rest on formalistic distinctions rather than actual market realities are generally disfavored in antitrust law. This Court has preferred to resolve antitrust claims on a case-by-case basis, focusing on the particular facts disclosed by the record . . . In determining the existence of market power, and specifically the responsiveness of the sales of one product to price changes of the other, this Court has examined closely the economic reality of the market at issue.") (internal citations omitted). REDACTED

Accordingly, on these facts, any compensable injury to direct purchasers that resell TriCor is measured by their "lost profits" (if any)—that is, the amount of profit they lost by buying and reselling TriCor products, as compared to buying and reselling statins. REDACTED

Plaintiffs cite cases that they allege are "analytically identical." *See* DP Br. At 2. But these cases do *not* address the market place dynamics that would exist in the "but for" world

posited by plaintiffs. In *In re Cardizem CD Antitrust Litigation*, 200 F.R.D. 297, 309 (E.D. Mich. 2001), the manufacturers argued that plaintiffs could not pursue an "overcharge" case because (1) the purchasers were resellers and (2) there was a choice between two different products in the "but for" world (the brand and the generic). The court rejected that argument as "at variance" with *Hanover Shoe, Inc. v. United Shoe Mach. Corp*, 392 U.S. 481 (1968) and *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977).

Defendants' argument here does not rely on either argument put forth by the *Cardizem* defendants. Defendants do not rely on the fact that the members of the proposed DP Class are resellers, nor or the fact that there was a choice between TriCor and an AB-rated generic version of TriCor in the "but for" world. To the contrary, defendants simply assert that under Plaintiffs *own* theory of the case, the prescriptions in the "but for" world would *not* reflect a choice between TriCor and an AB-rated generic version. In *Cardizem*, the manufacturers did not contend that the purchases in their "but for" world would predominately be a third product rather than the brand drug or an AB-rated generic version. Plaintiffs try to have it both ways – they allege that generics would take over in spring 2002 ***and*** that fenofibrate usage would grow fourfold in such a situation. They cannot support this allegation.

The difference between Defendants' argument and the argument in *Cardizem* is crucial. The economic structure of an "overcharge" case requires either a) a purchase of the brand product in the "but for" world at a lower price than in the actual world or b) a purchase of a fungible product in the "but for" world at a lower price that the price of the brand product in the actual world. REDACTED

Defendants' facts do not raise a mere "disagreement" among experts concerning the proper measure of damages, and this issue should not be set aside by the Court at the class certification stage. *In re Cardizem* at 311. REDACTED

See Ex. 9

(Deposition Tr. of J. Leitzinger) at 131.[4] Because Dr. Leitzinger has not proposed an appropriate damages methodology that takes economic realities into account, plaintiffs have not satisfied their burden to show that the injury and damages in this case are susceptible to class-wide proof.

B. Plaintiffs' proposed damages methodology is flawed because it fails to account for the fact that many purchases in the "but-for" world would be for products other than fenofibrate.

Based on the allegations in the Complaint, no new TriCor formulations would be introduced in the "but-for" world. It is therefore a false premise that for every TriCor purchase in the "actual" world there would be a purchase of generic fenofibrate in the "but-for" world, and therefore, that an overcharge should apply to *each* purchase of TriCor by members of the class during the class period. This ignores the facts of the case, the realities of the fenofibrate and prescription drug market, and the presence of significant "non-conspiratorial factors" in pricing in the "but-for" world.

---

[4] REDACTED

"Non-conspiratorial factors" in price must be considered in order to accurately determine "but-for" pricing. Areeda explains:

> If something has changed--in addition to the fact of collusion--this must be taken into account in estimating the "but for" prices during the conspiracy period.
>
> * * *
>
> Although one may be quite confident that there was no collusion during that period, some things may well have changed. For example, the product itself is apt to change over time. All else being equal, product improvements may require higher prices because of higher costs. *Moreover, product improvements that consumers presumably value will lead to shifts in the demand, which will also influence price. As the supply-and-demand conditions evolve over time, the plaintiff is forecasting outside the sample range--that is, the regression model estimates the relationship between supply and demand variables during one period while the forecast pertains to supply and demand variables that have not been incorporated in the estimation procedure. As a statistical matter, this tends to increase the standard errors of the estimates. In essence, the estimates are less precise.*

2 Philip R. Areeda and Herbert Hovenkamp, Antitrust Law at 394(b). (emphasis added).

As described above, introduction of an AB-rated generic version of TriCor would end Abbott's detailing of TriCor. REDACTED

Defendants' success in increasing sales for TriCor has been driven by product improvements (the TriCor 160 mg tablets and the "No Food Effect" TriCor 145 mg tablets) and by the deployment of over a thousand sales representatives to explain those improvements to physicians. REDACTED

Because many prescriptions in the "but-for" world would not have been written for TriCor or for any fenofibrate product, plaintiffs' theory, which rests on the assumption that every "real world" TriCor prescription would have been 1) written for TriCor and 2) filled with a generic fenofibrate product in the "but for" world, is fatally flawed.

Moreover, Defendants know there are certain physicians and patients who choose branded prescription drugs over available AB-rated generic versions. Those physicians and patients are not sensitive to the price differential between a brand drug and its AB-rated generic version, and as a result that differential can be increased by the brand name manufacturer without losing additional sales to the AB-rated generic version. Because of this phenomenon, REDACTED

Because of this pricing behavior, some class members would actually pay *more* for TriCor in the but-for world. The Third Circuit has affirmed the denial of class certification when the factors affecting each class member's injury are so complex that the determination of an individuals harm would be a "Herculean task." *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 187 (3d Cir. 2001) (affirming the denial of class certification in a securities litigation).[5]

[5] Differences in the *amount* of class members' damages ordinarily will not preclude class certification. "On the other hand, where the issue of damages does not lend itself to such a mechanical calculation, but requires separate mini-trials of an overwhelming large number of individual claims," courts have found that class certification should be denied. *Windham v. American Brands, Inc.*, 565 F.2d 59, 68 (4th Cir. 1977) (summarizing cases); *see also Lienhart v. Dryvit Systems, Inc.*, 255 F.3d 138, 147 (4th Cir. 2001) ("[I]t is (continued . . .)

Any assertion that individualized issues of damages can be determined at a future stage of the case is improper, since it ignores the requirements of the federal rules and, as one court has noted, would "merely delay[] resolution of the problem until a later date." *Windham v. Am. Brands, Inc.*, 565 F.2d 59 at 72 (citations omitted). Even where liability and damages are bifurcated, "the problem of determining the fact and amount of damage" for each indirect purchaser remains, and is simply delayed until later in the proceeding. *Keating v. Philip Morris, Inc.*, 417 N.W.2d 132, 138 (Minn. App. 1987).

C. A "lost profits" case could not be certified as a class action on the facts of this case.

Without a viable overcharge theory, class certification is impossible. The alternative of lost profits is no answer. Such claims have been characterized by many courts as inherently individualized and not appropriate for class treatment. *See, e.g. Broussard v. Meineke Discount Muffler Shops, Inc.*, 155 F.3d 331, 342-43 (4th Cir. 1998) (holding that "each putative class member's claim for lost profits damages was inherently individualized and thus not easily amenable to class treatment"); *Boley v. Brown*, 10 F.3d 218, 223 (4th Cir. 1993) (the calculation of lost profits is too "dependent upon consideration of the unique circumstances pertinent to each class member" to allow case to proceed as a class action); *Bell Atlantic Corp. v. AT&T Corp.*, 339 F.3d 294, 306 (5th Cir. 2003) (rejecting class certification based on a lost profits argument because "any reasonable approximation of the damages actually suffered by the various class members would instead require a much tighter inquiry into the nature of the class member businesses"); *Jim Moore Ins. Agency, Inc. v. State Farm Mut. Auto. Ins. Co.*, 2003 WL 21146714

(. . . continued)

impermissible to determine damages on a classwide basis in order to facilitate class treatment of a case when the governing law requires individualized proof of damages.").

at 9 (S.D. Fla. 2003) (rejecting certification of a "lost-profits" class as "resulting in a multitude of highly individualized determinations"). In this case, the analysis of each class member's alleged "lost profits" would require a detailed, complex, and highly individualized inquiry into that class member's business models, profit margins, costs, practices and policies, making class certification inappropriate.[6]

D. Plaintiffs have not shown that each class member was injured.

Where some members of a proposed class have not suffered an injury, class certification is inappropriate because plaintiffs cannot demonstrate class wide impact. *See In re Agricultural. Chems. Antitrust Litig.*, 1995-2 Trade Cas. ¶ 71, 197, 1995 WL 787538, at *4 (N.D. Fla. 1995) ("[I]mpact may be demonstrated on a class-wide basis only if the common proof demonstrates some damage to each class member); *see also Datagate, Inc. v. Hewlett-Packard Co.*, 941 F.2d 864, 868-69 (finding no injury in fact where plaintiff benefited from the alleged antitrust injury); *Belcher Oil Co. v. Fla. Fuels Inc.*, 749 F. Supp. 1104, 1108 (S.D. Fla. 1990) (same).

Plaintiffs allege that they were injured by the absence of an AB-rated generic to TriCor. If such a product had been available, plaintiffs contend that they would purchased those lower priced products and would be better off financially. Plaintiffs ignore the financial realities within the pharmaceutical industry and differences within the class, which includes large and small wholesalers and retailers, who likely use varying formulas and strategies for determining pricing.

---

[6] Because Plaintiffs have already taken the position that they are not required to provide defendants with discovery on their profit margins or costs, they should be precluded from pursuing a theory of lost profits in any event.

The named plaintiffs are small regional wholesalers. These companies almost certainly use different pricing strategies than other companies within their putative class, companies that account for a far larger portion of direct purchases of TriCor. As an initial matter, these small wholesalers could not be more different from massive, national mail-order and retail pharmacies like Wal-Mart and Medco. REDACTED

The Big Three generally operate on a "cost-plus" basis, meaning they charge their customers the same percentage mark-up on their wholesale acquisition price regardless of whether the product is a generic or a brand-name product. In fact, REDACTED

See Ex. 10 (Affidavit of Joshua M. Gordon) at 1. Under this pricing strategy, the higher the acquisition cost, the higher the cost-plus price and resulting profits.

Because the acquisition price for brand-name products is generally higher – in some cases exponentially so – than the price for generics, the Big Three stand to *profit* from the absence of an AB-rated generic alternative to a brand-name drug product; in other words, they were ***benefited***, not harmed, by the alleged conduct. In addition, the phenomenon of "generic bypass"—a market condition in which many retailers purchase generic products directly from manufacturers and from small regional wholesalers, "bypassing" the major wholesalers and depriving them of the ability to profit—also means that the "Big Three" may have actually *lost* revenue in the "but-for" world in which an AB-rated generic replaced TriCor.

These facts create a conflict within the class and further mean that the plaintiffs are unable to demonstrate antitrust injury on a class-wide basis. *See Valley Drug Co. v. Geneva*

Pharmaceuticals, Inc., 350 F.3d 1181, 1190-91 (11th Cir. 2003) (holding that a conflict precluding class certification could be created by evidence showing that the "big three" wholesalers operate on "cost-plus" basis or are subject to "generic bypass" and therefore stand to profit from the absence of generic competition); *In re Terazosin Hydrochloride Antitrust Litigation*, 223 F.R.D. 666 (S.D. Fla. 2004) (on remand, holding that failure of plaintiffs to provide evidence concerning effects of cost-plus structure or generic bypass precluded class certification).

Plaintiffs simply cannot demonstrate "class wide impact" because some class members have not been injured by the challenged conduct.[7] It is plaintiffs' burden to prove that damages are susceptible to class-wide proof. Their proposed methodology fails to satisfy that burden.

III. PLAINTIFFS CANNOT SATISFY THE "PREDOMINANCE" INQUIRY OF RULE 23, BECAUSE INDIVIDUALIZED QUESTIONS OF FACT PREDOMINATE OVER COMMON ISSUES.

A. Differently-situated plaintiffs cannot present the same facts to establish the type, nature, and amount of their injuries.

1. The power to influence prescribers constitutes a profound difference between members of the class that should preclude class certification.

The power of certain categories of direct purchasers to influence prescribers should preclude certification of the Proposed DP Class. Plaintiffs relegate this obvious obstacle to class certification to a single sentence and a footnote. *See* DP Brief at 18 n. 18.

[7] Defendants have not been allowed to take discovery on this pricing issue, so it is impossible to know who many of the other member of the class actually benefited from the absence of an AB-rated generic to TriCor, and did not suffer an injury. Defendants respectfully request that the Court permit discovery on these issues.

The issue in this case is not merely that there are "categories" of direct purchasers with "different purchasing positions." *Cf. In re Bulk Extended Graphite Products Antitrust Litigation*, 2006 WL 891362 at *6 (D.N.J. April 4, 2006). The issue in this case is the power of some categories of direct purchasers of TriCor throughout the proposed class period to determine (a) whether they will buy TriCor *at all* and (b) if they do buy TriCor, the price at which they will buy it.[8] On the unique facts of this case, the power has been magnified by the choice available between TriCor products and other fenofibrates—as well as fibrates (Gemfibrozil/ Lopid), niacins, and statins.

In this case, plaintiffs' "common evidence" of Defendants' conduct does not establish that there was a common *impact* on the direct purchasers. Common evidence of Defendants' alleged conduct *by itself* will not show—contrary to plaintiffs' assertions—that "Defendants' scheme caused all members of the Class to suffer antitrust injury, *i.e.*, overpay for fenofibrates." DP Brief at 12. Evidence of broad market trends after entry of AB-rated products and evidence of net prices before and after entry of AB-rated generic products will *not* show a common impact of Defendants' alleged scheme on specific categories of direct purchasers of TriCor. *See, e.g., Melnick v. Microsoft Corp.*, No. V-99-709, CV-99-752, 2001 WL 1012261 *11 (Me. Super. Ct. Aug. 24, 2001) ("[t]he fact that a defendant has engaged in illegal conduct is only one of several elements of class action certification") *citing Dry Cleaning & Laundry Inst. of Detroit, Inc. v. Flom's Corp.*, 1993 WL 527928, at *1 (E.D. Mich. Oct. 19, 1993).

Plaintiffs argue that their demand is derivative, and that therefore they are similarly situated for purposes of this case. This theory is based on a faulty and oversimplified

[8] In *In re Bulk Graphite*, there was no indication that the different prices paid by the direct purchasers were the result of negotiating power of the direct purchasers. *Id.*

view of the market for prescription drugs. In fact, as described above, many entities within the proposed class have the ability to drive demand for prescription drugs. Given that the plaintiffs have expressly pleaded that the new TriCor formulations had no therapeutic benefit over the older products, there is no reason they could not have attempted to shift prescriptions to available, cheaper, alternative products. REDACTED

In *Continental Orthopedic Appliances, Inc. v. Health Ins. Plan of Greater New York, Inc.*, 198 F.R.D. 41 (E.D.N.Y. 2000), the court explained that non-conspiratorial factors—including differences in business models, the size and financial situation of various plaintiffs, the geographic location of the plaintiffs, and their relative abilities to reduce or mitigate their damages—precluded class certification where those differences, as here, necessitated individualized inquiry:

> At this stage of the proceedings, the Court finds that, with reasonable certainty, the plaintiffs cannot offer common proof establishing that but for the antitrust violation, they would not have suffered their injuries. In this litigation, neither the services or their distributors are standard. Rather, the class includes businesses of all sizes, each of which was in a different financial position at the time of the alleged violation. Thus, the alleged damages suffered by the [plaintiffs] could be the result of any number of factors.
>
> * * *
>
> Here, damages are directly linked to causation, and are, therefore, subject to the same difficulties of class-wide determination described above. The amount of damages suffered by each plaintiff

> will depend on a variety of factors, including the types of services and devices the business provided; the geographic location of the business; the number of [defendant's] patients the business served; and the percentage of profit that originated from the contract they no longer maintained with [defendant]. In addition, the defendants intend to introduce evidence that some plaintiffs never attempted to mitigate their damages. The Court finds that the computation of damages in this case would not be mechanical but rather would be a complex, highly individualized task, requiring separate "mini-trials" of a large number of claims.
>
> In sum, although this suit involves allegations of a common antitrust violation, it also involves highly individualized issues of both injury and damages. The individualized issues so overwhelm the common ones that the predominance requirement of Rule 23(b)(3) is not met. Accordingly, the motion for class certification is denied.

Id. at 47-48. The same analysis applies here. The fact that members of the class are differently situated with respect to their ability to control the nature and extent, if any, of their injury and damages will necessitate a case-by-case analysis of the circumstances surrounding each plaintiff's ability to affect the prescriptions of fenofibrate products.

IV. AN ASSIGNEE IS NOT A PROPER PLAINTIFF.

One named plaintiff in this case, Meijer Inc., is actually an indirect, not a direct purchaser. Meijer purports to bring its claims as an assignee of a direct purchaser, Frank W. Kerr Co. But as an assignee of claims, rather than an actual class member, Meijer cannot represent the class, and is improperly named as a plaintiff. *See In re Public Offering Fee Antitrust Litigation*, No. 98 Civ. 7890(LMM), 00 Civ. 7804(LMM), 2006 WL 1026653 at * 4 (S.D.N.Y. 2006) (rejecting an assignee of claims as a class representative because it is improper to "treat class membership as a transferable asset"). Therefore, at least one named representative is incapable of representing the class.

V. THE CLASS ACTION MECHANISM IS NOT NECESSARY TO ADDRESS INJUNCTIVE RELIEF IF SUCH RELIEF IS WARRANTED.

With respect to plaintiffs' injunctive claims, a class action is not superior to other methods of adjudication, because the nature of the relief that plaintiffs seek is such that any relief obtained by one plaintiff in a single action (or a competitor such as Teva) would inure to the benefit of all indirect purchasers, and therefore a class action, with its attendant complexities, cost, and delay, provides no additional benefit with respect to injunctive relief.

The injunctive relief plaintiffs seek is directed towards Abbott and Fournier's general conduct, and not actions taken towards members of the class individually. Hence, there is no need to certify a class for injunctive relief. Courts have recognized that where the precise relief sought by a class is likely to be obtained in traditional bipolar litigation, there is no need to undertake the complexity, expense and burden of a class action. *See Access Now Inc. v. Walt Disney World Co.*, 211 F.R.D. 452, 455 (M.D. Fla. 2001) ("[t]he complexity and expense of a class action is not necessary" where "plaintiffs may achieve by injunction all relief which would inure to similarly situated persons without the necessity of class certification"); *Kow v. New York City Hous. Auth.*, 92 F.R.D. 73, 74 (S.D.N.Y. 1981) (there is no benefit to having a class when there is no reason to doubt that the defendants would accord to all members of the proposed class the benefits of any judgment accorded to the plaintiff.") (internal citations omitted); *Dionne v. Bouley*, 757 F.2d 1344, 1356 (1st Cir. 1985) (upholding the denial of class certification to a class seeing injunctive relief "on the ground that any injunctive or declaratory relief will inure to the benefit of all those similarly situated").

There are a number of related, non-class-action cases pending before this Court (*e.g.*, actions by Teva, Impax, CVS, Walgreens, and Pacificare) that are premised on the same allegations raised in this class action. These parallel actions seek the same injunctive relief

sought in this case. If defendants' conduct is found unlawful in any one of those cases, and an injunction is granted, all members of the proposed class will benefit, regardless of whether class certification is granted in this case. Therefore, plaintiffs' claim for injunctive relief does not provide a basis for the certification of the proposed class.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court deny the motion to certify the Proposed DP Class.

Attorneys for Abbott Laboratories:

/s/ Mary B. Graham

Mary B. Graham (I.D. #2256)
James W. Parrett, Jr. (#4292)
MORRIS, NICHOLS, ARSHT & TUNNELL
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19801
302.658.9200

OF COUNSEL:

William F. Cavanaugh, Jr.
Thomas W. Pipport
Chad J. Peterman
Alexis A. Gander
PATTERSON, BELKNAP, WEBB TYLER LLP
1133 Avenue of the Americas
New York, NY 10036-6710
212.336.2000

Attorneys for Fournier Industrie et Santé and Laboratories Fournier S.A.:

/s/ Anne Shea Gaza

Frederick L. Cottrell, III (I.D. #2555)
Anne Shea Gaza (I.D. #4093)
cottrell@rlf.com
gaza@rlf.com
RICHARDS, LAYTON & FINGER
One Rodney Square
Wilmington, DE 19801
302.651.7700

OF COUNSEL:

Steven C. Sunshine
Maria M. DiMoscato
CADWALADER, WICKERSHAM & TAFT LLP
1201 F Street, N.W.
Washington, DC 20004
202.862.2200

Matthew P. Hendrickson
Bradley J. Demuth
CADWALADER, WICKERSHAM & TAFT LLP
One World Financial Center
New York, NY 10281
212.504.6000

Timothy C. Bickham
STEPTOE & JOHNSON LLP
1330 Connecticut Avenue, N.W.
Washington, DC 20036-1795
202.429.5517

Dated: August 16, 2006
532841

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on May 13, 2008, the foregoing was caused to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

In addition, the undersigned hereby certifies that true and correct copies of the foregoing were caused to be served via electronic mail on May 13, 2008 upon the following parties:

REPRESENTING DIRECT PURCHASER CLASS PLAINTIFFS (LOUISIANA WHOLESALE, ROCHESTER DRUG, MEIJER) (C.A. 05-340)	Jeffrey S. Goddess **jgoddess@rmgglaw.com** Bruce E. Gerstein **bgerstein@garwingerstein.com** Barry S. Taus **btaus@garwingerstein.com** Adam M. Steinfeld **asteinfeld@garwingerstein.com** Daniel Berger **danberger@bm.net** Eric L. Cramer **ecramer@bm.net** Peter Kohn **pkohn@bm.net** Linda P. Nussbaum **lnussbaum@kaplanfox.com** Stuart Des Roches **stuart@odrlaw.com**
REPRESENTING WALGREEN, ECKERD, KROGER, MAXI (C.A. 05-340)	Elizabeth M. McGeever **emmcgeever@prickett.com** Scott E. Perwin **sperwin@kennynachwalter.com**
REPRESENTING CVS, RITE AID (C.A. 05-340)	Elizabeth M. McGeever **emmcgeever@prickett.com** Joseph T. Lukens **jlukens@hangley.com** Steve D. Shadowen **sshadowen@hangley.com**

REPRESENTING AMERICAN SALES COMPANY INC. (C.A. 05-340)	Elizabeth M. McGeever **emmcgeever@prickett.com** Scott E. Perwin **sperwin@kennynachwalter.com**
REPRESENTING INDIRECT PURCHASER CLASS PLAINTIFFS (C.A. 05-360)	A. Zachary Naylor Pamela S. Tikellis Thomas M. Sobol Patrick E. Cafferty Jeffrey L. Kodroff Bernard J. Persky Mike Gottsch Brian Clobes Michael Tarringer Tim Fraser David Nalven Greg Matthews Christopher McDonald Kellie Safar Theodore M. Lieverman Pat Howard **tricor@chimicles.com**
REPRESENTING PACIFICARE (C.A. 05-360)	Jonathan L. Parshall **jonp@msllaw.com** William Christopher Carmody **bcarmody@susmangodfrey.com** John Turner **jturner@susmangodfrey.com** Shawn Rabin **srabin@susmangodfrey.com** Justin Nelson **jnelson@susmangodfrey.com** Ken Zylstra **zylstra@verizon.net** Mark Sandman **mms@rawlingsandassociates.com** Jeffrey Swann **js5@rawlingsandassociates.com**

REPRESENTING TEVA PHARMACEUTICALS (C.A. 02-1512)	Josy W. Ingersoll Karen E. Keller Bruce M. Gagala Christopher T. Holding Ken Cohen Elaine Blais **tricor@ycst.com**
REPRESENTING IMPAX LABORATORIES (C.A. 03-120)	Mary Matterer **mmatterer@morrisjames.com** Asim Bhansali **abhansali@kvn.com**
REPRESENTING FOURNIER (ALL CASES)	Frederick L. Cottrell, III Anne Shea Gaza Steven C. Sunshine Matthew P. Hendrickson Bradley J. Demuth Maggie DiMoscato Timothy C. Bickham **tricor@rlf.com**

/s/ James W. Parrett, Jr.

James W. Parrett, Jr. (#4292)

520842

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on May 13, 2008, the foregoing was caused to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

In addition, the undersigned hereby certifies that true and correct copies of the foregoing were caused to be served via electronic mail on May 13, 2008 upon the following parties:

REPRESENTING DIRECT PURCHASER CLASS PLAINTIFFS (LOUISIANA WHOLESALE, ROCHESTER DRUG, MEIJER) (C.A. 05-340)	Jeffrey S. Goddess **jgoddess@rmgglaw.com** Bruce E. Gerstein **bgerstein@garwingerstein.com** Barry S. Taus **btaus@garwingerstein.com** Adam M. Steinfeld **asteinfeld@garwingerstein.com** Daniel Berger **danberger@bm.net** Eric L. Cramer **ecramer@bm.net** Peter Kohn **pkohn@bm.net** Linda P. Nussbaum **lnussbaum@kaplanfox.com** Stuart Des Roches **stuart@odrlaw.com**
REPRESENTING WALGREEN, ECKERD, KROGER, MAXI (C.A. 05-340)	Elizabeth M. McGeever **emmcgeever@prickett.com** Scott E. Perwin **sperwin@kennynachwalter.com**
REPRESENTING CVS, RITE AID (C.A. 05-340)	Elizabeth M. McGeever **emmcgeever@prickett.com** Joseph T. Lukens **jlukens@hangley.com** Steve D. Shadowen **sshadowen@hangley.com**

REPRESENTING AMERICAN SALES COMPANY INC. (C.A. 05-340)	Elizabeth M. McGeever **emmcgeever@prickett.com** Scott E. Perwin **sperwin@kennynachwalter.com**
REPRESENTING INDIRECT PURCHASER CLASS PLAINTIFFS (C.A. 05-360)	A. Zachary Naylor Pamela S. Tikellis Thomas M. Sobol Patrick E. Cafferty Jeffrey L. Kodroff Bernard J. Persky Mike Gottsch Brian Clobes Michael Tarringer Tim Fraser David Nalven Greg Matthews Christopher McDonald Kellie Safar Theodore M. Lieverman Pat Howard **tricor@chimicles.com**
REPRESENTING PACIFICARE (C.A. 05-360)	Jonathan L. Parshall **jonp@msllaw.com** William Christopher Carmody **bcarmody@susmangodfrey.com** John Turner **jturner@susmangodfrey.com** Shawn Rabin **srabin@susmangodfrey.com** Justin Nelson **jnelson@susmangodfrey.com** Ken Zylstra **zylstra@verizon.net** Mark Sandman **mms@rawlingsandassociates.com** Jeffrey Swann **js5@rawlingsandassociates.com**

REPRESENTING TEVA PHARMACEUTICALS (C.A. 02-1512)	Josy W. Ingersoll Karen E. Keller Bruce M. Gagala Christopher T. Holding Ken Cohen Elaine Blais **tricor@ycst.com**
REPRESENTING IMPAX LABORATORIES (C.A. 03-120)	Mary Matterer **mmatterer@morrisjames.com** Asim Bhansali **abhansali@kvn.com**
REPRESENTING FOURNIER (ALL CASES)	Frederick L. Cottrell, III Anne Shea Gaza Steven C. Sunshine Matthew P. Hendrickson Bradley J. Demuth Maggie DiMoscato Timothy C. Bickham **tricor@rlf.com**

/s/ James W. Parrett, Jr.

James W. Parrett, Jr. (#4292)

520842